Correspondence

Stimulated Gracilis Neosphincter Clinical Trial

TO THE EDITOR: Fecal incontinence is a common but debilitating condition. Fortunately, many cases can be treated medically, with an adequate control of symptoms. In some patients, however, the symptoms are such that colostomy is considered. In patients in whom an anatomic separation exists in the sphincter mechanism, surgical repair gives good results, provided there is no associated neuropathy or myopathy. In patients in whom the primary disorder is a myopathy or neuropathy, current surgical procedures frequently fail. The graciloplasty, a procedure in which the gracilis muscle is transposed from the thigh to encircle the anus, leaving its vascular and neural supply intact, is one such procedure.

The gracilis is composed of type II muscle fibers, which are fast-twitch, easily fatigued fibers. The external sphincter is primarily composed of type I fibers, which are slow-twitch, fatigue-resistant fibers. This allows the external sphincter to function in a steady state of contraction.

It has been shown that low-frequency electrical stimulation of a type II muscle will convert it to a predominantly type I muscle.[1] A totally implantable generator has been developed for this purpose, and the preliminary results in England have been favorable. Williams and coworkers reported on a group of 12 patients who had intact anal sphincters and substantial incontinence for solid, liquid, and gas. Postoperatively, 9 patients were incontinent only for flatus, and 3 patients were incontinent for flatus and occasional liquid feces. No patient was incontinent for solid feces.[2]

The Food and Drug Administration has allowed clinical trials to begin in the United States, initially restricted to five institutions, to verify the results of that trial. The procedure is done in three stages. The first stage consists of a vascular-delay procedure whereby two to three vascular branches supplying the distal aspect of the gracilis muscle are divided to allow for the development of collaterals. At this stage, a diverting stoma is carried out. The second stage is performed about four weeks later. During this procedure, the graciloplasty is done and the electrical stimulator implanted so that the main nerve to the gracilis is stimulated. The conversion process is then started. The implantable stimulator is programmed during routine office visits using an external programmer. Stimulation is started with high-frequency intermittent stimulation, and this is gradually changed to continuous low-frequency stimulation. This process requires about three months. The third stage consists of stomal closure. The stimulator works continuously until such time as the patient needs to evacuate. Placing a magnet over the stimulator interrupts the stimulation, the patient evacuates, the magnet is removed, and stimulation resumes.

Using current techniques, the complication rate is acceptable. The complications specific to this procedure include muscle necrosis, lead dislodgement, infection, and rare cases of a neuralgic type of discomfort following the course of the cutaneous branch of the obturator nerve. This appears to be a self-limiting condition.

Patients suitable for the technique are those with traumatic, myopathic, or neuropathic incontinence that has been unresponsive to medical management. Also, patients who remain incontinent after having undergone pull-through procedures for congenital abnormalities are candidates. They should be psychologically stable and in reasonably good health to allow for valid long-term follow-up. If a patient suffers from the diarrheal form of the irritable bowel syndrome, this must be under good control. Patients excluded from the study include those younger than 16 years or older than 75 years of age. Also excluded are patients who have generalized neurologic disorders such as multiple sclerosis, severe arthritis, disseminated carcinoma or a short life expectancy, residual local malignant disease in the pelvis, a history of abdominal or perineal radiation, a demand cardiac pacemaker, perineal sepsis, Crohn's disease, or who demonstrate an inability to understand the nature of the procedure. Pregnancy is also a contraindication.

Physicians or patients who would like additional information about the procedure should contact me.

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Dinoprostone Cervical Gel

TO THE EDITOR: In the investigation reported by Gilson and co-workers, it was found that preinduction treatment with 0.5 mg of dinoprostone (prostaglandin E_2 [PGE_2]) given endocervically did not reduce the rate of cesarean section.[1] Indeed, the rate was more than twice as great in the treated women as in the controls, 39% compared with 16%. As noted by the authors, this finding is at variance with that of other studies. In two large registration trials conducted by Upjohn Laboratories in which the company's recently marketed Prepidil Gel (dinoprostone cervical gel, 0.5 mg) was used, there was a downward trend in the rate of cesarean delivery in PGE_2-treated patients, although the difference did not reach statistical significance.[2,3]

Of greater interest were the authors' findings of no change in the Bishop score and no difference in the interval from induction to delivery. This again is in contrast to the results obtained in studies supporting Prepidil Gel registration that clearly showed a beneficial drug effect as regards these two important indices. Although the PGE_2 used in Gilson's study was identified with the Upjohn